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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,604	02/20/2002	Thomas Kruger	70363	7284
7590	09/22/2004		EXAMINER	
McGLEW AND TUTTLE, P.C. SCARBOROUGH STATION SCARBOROUGH, NY 10510-0827				RAGONESE, ANDREA M
		ART UNIT	PAPER NUMBER	3743

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/079,604	KRUGER ET AL.
	Examiner	Art Unit
	Andrea M. Ragonese	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 July 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/20/02</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of invention I, drawn to **claims 1-11**, in the reply filed on July 26, 2004 is acknowledged. The traversal is on the ground(s) "that any unit which writes and reads a set of data requires a controlling device which gives a set of [instructions] to read and write in a certain manner to a unit." This argument is found persuasive. Therefore, the restriction requirement of June 29, 2004 is withdrawn. Subsequently, this Office action addresses all the originally presented **claims 1-20** on the merits.

Specification

2. The abstract of the disclosure is objected to because of the following typographical error: in line 3, "Ventilation," should be deleted and – Ventilation), – inserted therefor. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 12-20** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, in **claim 12**, the phrase "a reading the data..." in line 10 on page 11 appears to be missing structural details necessary to define the metes and bounds of the claimed device, and as a result, renders the claim vague and indefinite.

5. Any rejections in this Office action have been made by applying any pertinent prior art in the field to the merits of the claimed invention as best understood by the Examiner.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-20** are rejected under 35 U.S.C. 102(b) as being anticipated by Gilmore et al. (US 5,931,160).

8. Regarding **claims 1-11**, Gilmore et al. discloses a medical engineering device system fully capable of being programmed to carry out the processes as claimed. Specifically, Gilmore et al. discloses a medical engineering device system, such as a ventilator control system **10**, that is programmed to

- 1) first, using a processor **22**, read data specifying a number of different available modes of operation (column 8, lines 31-35);
- 2) then write the data to a storage medium, such as a display controller **12** (column 8, lines 31-58); and
- 3) lastly, based on the data that is read by the embedded controller **14**, clear the available modes of operation using a processor **30** in order to operate the device **10** according to a patient's specific needs (column 8, line 59 through column 9, line 12).

9. Regarding **claims 12-20**, Gilmore et al. discloses a medical engineering device system comprising:

- a medical engineering device, such as a ventilator **10**, with a separate data storage medium element connection (column 8, lines 21-30);
- a separate data storage medium element, such as a display controller **12**, the storage medium **12** being any one of electronic, optical or magnetic storage medium connectable to the medical engineering device **10**, the storage medium element **12** having data that specify a number of different available modes of operation on the medical engineering device **10**, the data also determining the clearing of the available modes of operation on the medical engineering device **10** (column 8, lines 31-58);
- a connection **15** between the data storage medium element **12** and the medical engineering device **10** (column 8, lines 28-30);
- a data reading element, such as an embedded controller **14**, for reading data from the data storage medium element **12** by a writing and reading unit, such as a sensor monitoring system **19**, associated with the medical engineering device **10** (column 8, lines 59-66);
- and medical engineering device processor **30** clearing the available modes of operation on the medical engineering device **10** based on the reading of the data from the data storage medium element **12** (column 8, line 67 through column 9, line 12).

10. Regarding **claims 12-20**, the Examiner notes that Applicant has essentially claimed statements of intended use. Gilmore et al. discloses a system in which the claimed functional limitations can inherently be performed since the system utilizes a display controller 12 with a processor 22 in combination with an embedded controller 14 with a processor 30 that are capable of being programmed to perform the desired functions and data processing. These recitations are statements of intended use utilizing functional language, which may not be given patentable weight in apparatus claims. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function alone. See MPEP § 2114. Therefore, as broadly interpreted by the Examiner, the previously presented rejection is applied to **claims 12-20** based on the prior art of record. See *In re Swinehart*, 169 USPQ 226 (CCPA 1971); *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lichtenstein (US 4,464,172), Hillsman (US 4,984,158), Willemot et al. (US 5,560,353), Biondi et al. (US 6,158,432), Biondi et al. (US 6,463,930 B2), Jonson (US 6,578,575 B1) and Biondi et al. (US 6,584,973 B1) all disclose medical engineering devices fully capable of being programmed to carry out the processes as claimed.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragone** whose telephone number is (703) 306-4055. The examiner can normally be reached on Monday through Friday from 8 am until 4 pm.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR



Henry Bennett
Supervisory Patent Examiner
Group 3700

